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JCS44 U.S. PTO**UTILITY PATENT APPLICATION TRANSMITTAL
(Small Entity)***(Only for new nonprovisional applications under 37 CFR 1.53(b))*Docket No.
0184.00037Total Pages in this Submission
46**TO THE ASSISTANT COMMISSIONER FOR PATENTS****Box Patent Application
Washington, D.C. 20231**

Transmitted herewith for filing under 35 U.S.C. 111(a) and 37 C.F.R. 1.53(b) is a new utility patent application for an invention entitled:

SPINAL IMPLANT FIXATION ASSEMBLY

and invented by:

MARC RICHELSON

JCS560 U.S. PTO

09/280283

03/29/99

If a CONTINUATION APPLICATION, check appropriate box and supply the requisite information:☒ Continuation ☒ Divisional ☐ Continuation-in-part (CIP) of prior application No.: 08/831,112

Which is a:

☐ Continuation ☐ Divisional ☒ Continuation-in-part (CIP) of prior application No.: 08/734,520

Which is a:

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.: _____

Enclosed are:

Application Elements

1. ☒ Filing fee as calculated and transmitted as described below
2. ☒ Specification having 37 pages and including the following:
 - a. ☒ Descriptive Title of the Invention
 - b. ☒ Cross References to Related Applications *(if applicable)*
 - c. ☐ Statement Regarding Federally-sponsored Research/Development *(if applicable)*
 - d. ☐ Reference to Microfiche Appendix *(if applicable)*
 - e. ☒ Background of the Invention
 - f. ☒ Brief Summary of the Invention
 - g. ☒ Brief Description of the Drawings *(if drawings filed)*
 - h. ☒ Detailed Description
 - i. ☒ Claim(s) as Classified Below
 - j. ☒ Abstract of the Disclosure

UTILITY PATENT APPLICATION TRANSMITTAL (Small Entity)

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Application Elements (Continued)

3. ☒ Drawing(s) (when necessary as prescribed by 35 USC 113)

a. ☐ Formal b. ☒ Informal Number of Sheets 4

4. ☒ Oath or Declaration

a. ☐ Newly executed (original or copy) ☐ Unexecuted

b. ☒ Copy from a prior application (37 CFR 1.63(d)) (for continuation/divisional application only)

c. ☒ With Power of Attorney ☐ Without Power of Attorney

d. ☐ DELETION OF INVENTOR(S)

Signed statement attached deleting inventor(s) named in the prior application,
see 37 C.F.R. 1.63(d)(2) and 1.33(b).

5. ☒ Incorporation By Reference (usable if Box 4b is checked)

The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied
under Box 4b, is considered as being part of the disclosure of the accompanying application and is hereby
incorporated by reference therein.

6. ☐ Computer Program in Microfiche

7. ☐ Genetic Sequence Submission (if applicable, all must be included)

a. ☐ Paper Copy

b. ☐ Computer Readable Copy

c. ☐ Statement Verifying Identical Paper and Computer Readable Copy

Accompanying Application Parts

8. ☐ Assignment Papers (cover sheet & documents)

9. ☐ 37 CFR 3.73(b) Statement (when there is an assignee)

10. ☐ English Translation Document (if applicable)

11. ☐ Information Disclosure Statement/PTO-1449 ☐ Copies of IDS Citations

12. ☐ Preliminary Amendment

13. ☒ Acknowledgment postcard

14. ☒ Certificate of Mailing

☐ First Class ☒ Express Mail (Specify Label No.): EL 286 888 087 US

UTILITY PATENT APPLICATION TRANSMITTAL (Small Entity)

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Accompanying Application Parts (Continued)

15. ☐ Certified Copy of Priority Document(s) (if foreign priority is claimed)
16. ☐ Small Entity Statement(s) - Specify Number of Statements Submitted: _____
17. ☒ Additional Enclosures (please identify below):

Copy of Small Entity Status from parent case; copy of Assignment from parent case; copy of Declaration from parent case; marked-up copy of parent case, cancelling claims 1-34, 40 and 43-45

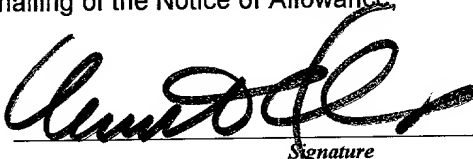
Fee Calculation and Transmittal

CLAIMS AS FILED

For	#Filed	#Allowed	#Extra	Rate	Fee
Total Claims	9	- 20 =	0	x \$9.00	\$0.00
Indep. Claims	4	- 3 =	1	x \$39.00	\$39.00
Multiple Dependent Claims (check if applicable) <input type="checkbox"/>					\$0.00
BASIC FEE					\$380.00
OTHER FEE (specify purpose) _____					\$0.00
TOTAL FILING FEE					\$419.00

- ☒ A check in the amount of \$419.00 to cover the filing fee is enclosed.
- ☒ The Commissioner is hereby authorized to charge and credit Deposit Account No. 11-1449 as described below. A duplicate copy of this sheet is enclosed.
- ☐ Charge the amount of _____ as filing fee.
- ☒ Credit any overpayment.
- ☒ Charge any additional filing fees required under 37 C.F.R. 1.16 and 1.17.
- ☐ Charge the issue fee set in 37 C.F.R. 1.18 at the mailing of the Notice of Allowance pursuant to 37 C.F.R. 1.311(b).

Dated: March 29, 1999


Signature

Kenneth I. Kohn, Reg. No. 30,955
30500 Northwestern Highway
Suite 410
Farmington Hills, Michigan 48334
(248) 539-5050

CC:

PATENT

Attorney's Docket Number: 0184.00005Applicant or Patentee: Marc Richelsoph

Serial or Patent No: _____

Filed or Issued: April 1, 1997For: SPINAL IMPLANT FIXATION ASSEMBLY

**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(f) and 1.27(d))--SMALL BUSINESS CONCERN**

I hereby declare that I am:

 the owner of the small business concern identified below: X an official of the small business concern empowered to act on behalf of the concern identified below:Name of Concern: Spinal InnovationsAddress of Concern: 9027 Summer Grove CoveCordova, TN 38018

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement: (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when, either directly or indirectly, one concern controls or has the power to control the other, or a third-party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention entitled:

SPINAL IMPLANT FIXATION ASSEMBLY

By Inventor(s): Marc Richelsoph

Described in:

 the specification filed herewith. X application serial no. _____, filed April 1, 1997. patent no. _____, issued _____.

If the rights held by the above-identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who could not qualify as a small business concern under 37 CFR 1.9(d) or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

* NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

NAME: _____

ADDRESS: _____

____ Individual ____ Small Business ____ Nonprofit Organization

NAME: _____

ADDRESS: _____

____ Individual ____ Small Business ____ Nonprofit Organization

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. [37 CFR 1.28(b)]

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Name of Person Signing: Marc Richelsoph
Title in Organization: Vice President for Research & Development
SPINAL INNOVATIONS
Address of Person Signing: 9027 Summer Grove Cove
Cordova, TN 38018

SIGNATURE: *Marc Richelsoph* Date: 8/12/97

(Small Entity-Small Business (Form 7-4)--Page 2 of 2)

SPINAL IMPLANT FIXATION ASSEMBLY

5

ABSTRACT

10 A spinal implant fixation assembly includes a bone fixation member, such as a screw or hook for fixation to a bone. A rod receiving seat is operatively connected to the bone fixation element for seating a portion of a rod therein. A locking mechanism, in the form of a nut and locking ring engage the rod receiving seat for forcing an inner wall of the rod receiving seat to contour around and engage the rod seated therein and for locking and fixing the rod relative to the inner housing. In one embodiment, the locking ring

15 secures a head portion of the bone fixation element within the assembly. A method is also provided for locking the rod to a bone by fixing a rod seating member to a bone and seating a portion of a rod within a substantially U-shaped seat of the seating member. The rod is then locked within the U-shaped seating member while engaging and contouring at least a portion of the

20 U-shaped seat about the rod. The assembly further includes a screw head receiving insert for obtaining a head of screw therein. The insert is moveable within the assembly between a locked position entrapping the screw head and an unlocked position wherein the screw head enters or escapes.

SPINAL IMPLANT FIXATION ASSEMBLY

TECHNICAL FIELD

5 The present invention relates to a implant fixation system and locking mechanism. More particularly, the present invention provides a locking mechanism, which can be multi-planar or fixed, for securing a rod to an implant.

10 BACKGROUND OF THE INVENTION

 Stabilization of the spine for various conditions, including degenerative disc disease, scoliosis, spondylolithises and spinal stenosis often require attaching implants to the spine and then securing the implants to spinal
15 rods. Such spinal fixation devices can immobilize the vertebrae and can alter the alignment of the spine over a large number of vertebrae by means of connecting at least one elongate rod to the sequence of selected vertebrae. Such rods can span a large number of vertebrae, such as three or four. However, the spine anatomy rarely allows for three or more implants to be
20 directly in line. In order to allow for this irregularity, the rod must be contoured to the coronal plane. With anatomical curvature in the saggital plane found in the lumbar spine, the rod has to be contoured in both planes, requiring considerable effort and surgical time.

For example, the U.S. Patents 5,554,157, issued September 10, 1996, 5,549,608 issued August 27, 1996, and 5,586,984 issued December 24, 1996, all to Errico et al. disclose polyaxial locking screw and coupling element devices for use with rod fixation apparatus. The '157 patent discloses a coupling element including an interior axial passage having an interior surface which is inwardly curvate at the lower portion thereof such that it comprises a socket for polyaxially retaining a spherical head of a screw. The coupling element further includes a pair of vertically oriented opposing channels extending down from the top of the coupling element which define therebetween a rod receiving seat. The channel further provides the walls of the upper portion to a pair of upwardly extending members, each including an exterior threading disposed on the upper most portion thereof for receiving a locking nut. During the implantation of the assembly, the locking nut seats against the top of the rod which in turn seats on top of the screw head. The nut causes the rod to be locked between the nut and screw and the screw to be locked in the socket.

The '608 patent discloses a modification wherein a locking ring is disposed about the exterior of the lower portion of the coupling element and provides an inward force on an outwardly tapered portion upon downward translation thereof causing the interior chamber to crush lock a screw head therein to eliminate the polyaxial nature of the screw element coupling.

The '984 patent discloses a polyaxial orthopedic device including a cutter element having a tapered lower portion including a slotted interior chamber in which a curved head of a screw is initially polyaxially disposed. The coupling element includes a recessed for receiving a rod of the implant apparatus. A locking ring is disposed about the lower portion of the coupling element and provides an inward force on the outwardly tapered portion upon downward translation thereof. The vertical slots are caused to close and crush and thereby locking the screw head within the interior chamber thereof.

In the prior art embodiments, the locking mechanism locks both the rod and screw head simultaneously. No prior art patent allows for the spherical head of the screw to be locked at a desired angle prior to rod insertion. Likewise the only surface locking the rod in place is the surface between either the seat and a locking nut or the rod entrapped between a locking ring and the seat.

It would be desirable to increase the area of contact of the locking mechanism about the rod as this is a high stress site secured only by a friction fit. It would also be desirable to lock the screw head in place prior to fixation of the rod.

SUMMARY OF THE INVENTION

In accordance with the present invention, there is provided a spinal implant fixation assembly including bone fixation means for fixation to
5 a bone and rod receiving means operatively connected to the bone fixation means. The rod receiving means includes a first seat having an inner wall for seating a portion of a rod therein. The assembly further provides locking means engaging the rod receiving means for forcing the inner wall to contour around and engage the rod seated therein and for locking and fixing the rod
10 relative to the inner housing.

The present invention further provides a method for locking a rod to a bone by the steps of fixing a rod seating member to a bone and then seating a portion of a rod within a substantially U-shaped seat of the seating member. The rod is locked within the U-shaped seat while engaging in
15 contouring at least a portion of the U-shaped seat about the rod.

The present invention further provides a spinal fixation assembly including screw head receiving means for retaining a head of a screw therein. The screw head receiving means is moveable within the assembly
20 between a locked position entrapping the screw head and an unlocked position wherein the screw head enters or escapes.

A method is further provided for retaining a screw head in a spinal fixation assembly by inserting a screw head into an expanded pocket of an insert contained within a first portion of an internal portion of a body member wherein the internal portion includes the first portion which is radially outwardly recessed relative to a second portion and then moving the insert into the second portion which compresses the pocket of the insert into a contracted condition to fixedly engage the screw head within the pocket.

BRIEF DESCRIPTION OF THE FIGURES

10

Other advantages of the present invention will be readily appreciated as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings wherein:

15

Figure 1 is a side view partially in cross section of a first embodiment of the present invention;

Figure 2 is a side view of a second embodiment of the present invention;

20

Figure 3 is a side exploded view of a third embodiment of the present invention;

Figure 4 is a cross sectional side view of the third embodiment of the present invention as assembled;

Figure 5 is a cross sectional view of a further embodiment of the present invention;

Figure 6 is a cross sectional view of the forth embodiment of the present invention and a screw member disposed adjacent the assembly;

5 Figure 7 shows the screw member inserted into the pocket of the forth embodiment of the present invention;

Figure 8 shows the screw member and a rod member locked within the assembly, the assembly being shown in cross section;

10 Figure 9 shows a side view, and cross section of the insert member;

Figure 10 shows a cross sectional view of the body portion of the forth embodiment of the present invention;

Figure 11 shows a cross sectional view of the assembly having straight rod disposed therein;

15 Figure 12 shows a cross section of the assembly having a curved rod disposed therein;

Figure 13 is side view of the insert member of the forth embodiment of the present invention;

20 Figure 14 shows a side view of a second embodiment of the insert member;

Figure 15 shows a cross sectional view of a second embodiment of the body portion of the forth embodiment;

Figure 16 is a side view of a third embodiment of the insert;

Figure 17 is a side view of a forth embodiment of the insert combining the embodiment of the insert combining the embodiment shown in Figures 14 and 16; and

5 Figure 18 is a cross sectional view of the third embodiment of the body portion.

DETAILED DESCRIPTION OF THE FIGURES

10 A spinal implant fixation assembly constructed in accordance with the present invention is generally shown at 10 in Figure 1. Similar structures amongst the several embodiments are shown by primed numbers in the various Figures.

More specifically, referring to the first embodiment of the
15 present invention generally shown at 10 in Figure 1, the assembly 10 includes a bone fixation element generally shown at 12 for fixation of the assembly 10 to a bone. A rod receiving mechanism is generally shown at 14 and is operatively connected to the bone fixation element 12. The rod receiving mechanism 14 includes a seat 16 having an inner wall 18 for seating a portion
20 of a rod 20 therein. A locking mechanism generally shown at 22 engages the rod receiving mechanism 14 for forcing the inner wall 18 to contour around and engage the rod 20 seated therein and for locking and fixing the rod 20 relative to the assembly 10. In this manner, as the locking mechanism 22

forces the inner wall 18 to contour around and engage the rod 20 seated therein, there is increased surface to surface contact and therefore increased frictional engagement between the seat 16 and rod 20 thereby providing a more effective frictional contact. That is, the inner wall 18 of the seat 16 is
5 compressed against the rod 20. The locking mechanism 22 is also seated against the rod 20. However, unlike prior art assemblies discussed above, the surface area engaging against the rod 20 is vastly increased over the prior art which increases the assembly to rod holding power.

More specifically, the rod receiving mechanism 14 includes a
10 tapered outer surface 24. As shown in the several embodiments, this outer surface 24 can be threaded. However, other means for securing the locking mechanism 22 can be used to achieve the same results. Preferably, the locking mechanism 22 is in the form of a nut member 26 having an inner surface 28, which can be threaded for use with the threaded outer surface 24 of the rod
15 receiving mechanism 14, for being forced over and engaging the outer surface 24 and inwardly deflecting the rod receiving mechanism 14 about the seat portion 16 as the locking member 26 further engages the tapered outer surface 14.

Referring more specifically to the rod receiving mechanism 14,
20 it includes a body portion 30 having two arms 32,34 extending therefrom and being substantially parallel relative to each other. The two arms 32,34 and the body portion 30 form a U-shaped inner surface defining the seat portion 16 thereof. Also, the arms 32,34 have the tapered threaded surface 24 about the

outer surface thereof. Thus, as the locking mechanism 22 in the form of the nut member 26 is threaded over the tapered outer surface 24 of the arms 32,34, the nut member 26 compresses the arms 32,34 against a rod member 20 disposed within the seat 16. As stated above, this provides a vastly increased surface area engagement between the seating surface 16, inner walls 18 and rod member 20. The arms 32,34 provide for flexibility, yet are sufficiently rigid to maintain structural integrity.

The tapered threaded portion 24 in combination with the nut member 26 provide a self-locking mechanism for securing the rod 20 thereto. By self-locking, it is meant that mere threading of the nut member 26 on the tapered surface 24 locks the nut member 26 in place. This locking mechanism is vibration resistant and has not been previously used in spinal implants. In combination with the other aspects of the present invention, the self-locking mechanism provides convenience of use and secure locking of the system along with flexibility of attachment of the rod and implant.

In the first embodiment shown in Figure 1, the bone fixation mechanism 12 is shown as a screw portion 36 extending integrally from the body portion 30. The body portion 30 includes a longitudinal axis. The bone fixation element 12, whether it is a screw portion as shown in Figure 1 at 36 or a hook portion 38 as shown in Figure 2, can either 1) lie along the axis so as to define a substantially linear element or 2) be angled relative to the longitudinal axis of the body portion 30. In this manner, the device can be adapted to various angulations between the bone connection surface and the

rod 20. These embodiments of the invention provide either a thread or hook portion 36,38, respectively, having the upper tapered threaded portion about the U-shaped seat 16. Variability of angulation is eliminated as each unit would be a solid fix piece. But the assemblies can be individually made in
5 various angulations. Such assemblies provide solid fixation of implants to the rod 20 where angulation is either not required or where known angulation may be repeatedly needed.

As stated above, the bone fixation element 12 can take on various shapes and sizes known in the art. The element 12 can have various
10 configurations as a screw 36 and various thread designs. Also, as shown in Figure 2, the hook portion 38 can be manufactured and used in a variety of hook sizes. Other shapes and sizes well known in the art can also be used.

The assembly is preferably made from machined titanium or alloy, but can be alternatively made from other types of cast or molded
15 materials well known in the art.

A second alternative embodiment of the present invention is shown in Figures 3 and 4. As stated above, double primed numbers are used to indicate like structure between the several embodiments.

Referring specifically to Figures 3 and 4, the bone fixation
20 element 12'' is shown as an independent screw member. The element 12'' includes a head portion 40 having a substantially spherical outer surface 42. The rod receiving mechanism 14'' is shown as a single integral unit including the first seat 16'' for receiving the rod member 20'' as discussed above between

the arms 32" and 34" and a second seating surface 44 having a substantially spherical shape for seating the head portion 40 of element 12" therein.

Referring more specifically to the rod receiving member 14", it consists of a substantially tubular body including the pair of spaced
5 substantially parallel arms 32",34" extending therefrom and forming the substantially U-shaped seat 16" as discussed above. The tubular body further includes a socket portion defining the second seat 44 which includes outwardly flaring flanges 46, as best shown in Figure 3. The outwardly flaring
10 flanges 46 have distal ends which flare radially outwardly relative to a central axis of the rod receiving member 14. The outer surfaces 50 define the outer surface of the second seat 44.

The head portion 40 and/or the seat 44 can have a textured surface for better gripping of the spherical outer surface 42. The textural surface can take on various forms, such as ripples abrasions or the like, which
15 increase the effective surface to surface contact and provide micro or macro grips against the outer surface 42.

The locking mechanism 22" of this embodiment includes the nut member 26" and a tubular sleeve member generally shown at 52. Although the nut member 26" and sleeve member 52 are shown as separate
20 elements, the present invention could be practiced where the nut member 26" includes a skirt portion integrally extending therefrom. In either embodiment, the sleeve 52 locks and fixes the head portion 40 of the screw element 12" within the seat 44 prior to the nut member 26" locking and fixing the rod 20"

within the seat 16". The sleeve member 52 includes an inner surface 54 which, upon being disposed over and about the outer surface 50 of the flanges 46, engages and inwardly deflects the distally outwardly tapering surfaces thereof to engage the socket portion of the seat 44 with the head portion 40 of the screw member 12". This can be accomplished prior to the connection of member 14" with the rod 20" and its locking in place by the nut member 26".

Referring more specifically to the sleeve member 52, it includes curved recessed portions 54 for seating of the rod member 20" therein in the assembled configuration as shown in Figure 4. The sleeve 52 also includes a skirt portion 56 which is disposed about the flanges 46 in the assembled position, as shown in Figure 4. In the embodiment shown in Figures 3 and 4, the element 30" includes the tapered threaded outer surface 24" which can be engaged by the threaded inner surface 28" of the nut member 26". As the nut member 26" is threaded over the outer tapered surface 24", it not only inwardly deflects the arms 32",34" to engage the rod member 20" but also forces the skirt portion 56 of the sleeve member 52 over the outwardly flared flanges 46 so as to force the inner surface of the seat 44 to frictionally engage and hold in place in a fixed manner the head portion 40 of the screw element 12". The screw element 12" is then locked securely at whatever angle the components are in. This locking is independent of the locking of the rod 20" in place.

This locking of the screw element can occur in two ways. The outer sleeve 52 can be pushed down with an instrument without the rod being

in place or pushed down as the nut 26" is tightened over the rod 20". This gives the surgeon the option of adjusting the screw angle for abnormal anatomy and locking it prior to locking the rod 20" to the assembly 10" or, alternatively, locking the screw element 12" and rod 20" interfaces
5 simultaneously when correction is not required.

As stated above, the head portion 40 is shown to be substantially spherical in shape. The seat 44 is a socket portion which is also substantially spherical for seating and engaging the head portion 40 therein. This allows for easy angular adjustment between the two components.
10 Alternatively, the head portion 40 of the screw element 12" can take on various other shapes, such as a square shape, which may not allow for similar angulation but would allow for similar connection between the head portion 40 and the seat 44 in accordance with the present invention.

In the embodiment as shown wherein the head portion 40 is of
15 a spherical shape for mating with the spherically shaped female seating portion 44, the configuration allows for up to 25° or more of angulation in all directions relative to the shaft portion 58 of the screw element 12". Thus, the present invention provides a multi-planar locking mechanism that allows for angulation in all planes. It also provides a locking mechanism that allows the
20 mechanism to be locked at any angle prior to rod insertion. Further results of the above is that the invention provides a multi-planar locking mechanism that reduces intraoperative rod contouring provides flexibility.

With more specific regard to the locking mechanism, the sleeve ring 52 includes an edge surface 58. The nut member 26" includes an abutment surface 60 for abutting against the edge 58 as the nut member 26" is threaded onto the tapered threaded portion 24" to force the ring member 52
5 over the outer surface of the flanges 50.

In operation, the screw element 12" is fixed onto a bone, the head portion 40 extending from the bone surface. The rod seating member 14" is then disposed over the head portion 40 of the screw element 12" by insertion of the head portion 40 into the seat 44. This is a snapping operation but allows
10 for angular adjustment of the tubular member 14" relative to the longitudinal axis of the screw element 12". The ring 52 is then disposed over the member 14" and an instrument is used to force the ring member 52 over the flanges 50 so as to lock the head portion 40 within the seat 44 thereby fixing the angulation between the two elements. The rod 20" is then seated within seat
15 16" of the member 14" as well as within the groove 54 of the ring 52. Finally, the nut member 26" is threaded over the tapered outer surface 24" of the arms 32",34" thereby fixing the rod 20" in frictional engagement within the seat 16" and against the nut member 26". Alternatively, as discussed above, the nut member 26" can be used to force the sleeve member 52 in place so as to lock
20 the head 40 and screw member 12" relative to the element 14".

Utilizing the embodiment of the present invention as shown in Figures 1 and 2, the process is exactly the same with regard to locking the rod

member 20 in place once the screw or hook portions 36,38, respectively, are connected to the known.

In view of the above, the present invention provides a method for locking a rod 20, 20" to a bone by the general steps of first fixing a rod seating member 14,14',14" to a bone and then seating a portion of the rod 20,20" within a substantially U-shaped seat 16,16" of the seating member 14,14',14". The rod 20,20" is locked within the U-shaped seat 16,16" while engaging and contouring at least a portion of the U-shaped seat 16,16" about the rod 20,20". As shown in Figures 3 and 4, this method can be more specifically defined by the steps of fixing the bone fixation member 12" to a bone and then locking and fixing the rod seating member 14" to the head portion 40 of the bone fixation member 12" and then locking the rod 20" within the U-shaped seat 16". The fixing step is accomplished by forcing the ring 52 over the outwardly flared portions 46 of the seat portion 44 to lock and fix the head portion 40 of the bone fixation element 12" therein. Finally, the locking of the rod is accomplished by locking the rod 20" within the U-shaped seat 16" by engaging the inner threaded surface 28" of the nut member 26" over the tapered outer threaded surface 24" of the U-shaped seat 16" to force the ring 52 over the outer surface 50 of the seat portion 44 to lock and fix the head portion 40 of the bone fixation element 12" therein while simultaneously deforming the inner surface of the U-shaped seat 16" about the rod 20" seated therein.

5 A further embodiment of the present invention is shown in
Figures 5-8. This embodiment of the invention includes the bone fixation
element generally shown at 12''', this embodiment being characterized by
including a screw head receiving insert generally shown at 70 which is
10 moveable within the assembly 10''' between a locked position as shown in
Figures 7 and 8 entrapping the screw head 40''' therein and an unlocked
position wherein the screw head 40''' enters or escapes, as shown in Figures 5
and 6. That is, this embodiment of the invention includes a single unit capable
of receiving a screw head 40''' therein and then allowing for polyaxial
15 adjustment of the screw head relative to the assembly and then locking of the
screw head within the assembly without requirement of additional elements to
the assembly. This embodiment of the invention drastically reduces surgical
time in spinal surgery and simplifies the elements needed for implementing the
bone fixation. Such a system is particularly useful when the rod 20''' is not
20 lined up with the screw 12'''.

More specifically, the assembly 10''' includes a body 30'''
including an internal portion 72'''. The internal portion 12''' generally
includes a first portion 74 which is radially outwardly recessed relative to a
second internal portion 76. The internal portion 74 can be effectively recessed
20 or actually recessed. The first portion could have a greater diameter than the
second portion or the second portion could be formed by flanges that extend
radially internally from an inner surface of the second portion thereby

effectively defining the end of each flange as the radially inwardly extending surface.

The screw head receiving means 70 consists of a insert member 70 including a seat 44''' for seating the screw head 40''' therein. The insert 70 is moveable within the internal portion 72 between the locked and unlocked position as discussed below.

Figure 9 shows an enlarged cross-sectional view of the insert 70 made in accordance with the present invention. The seat 44''' more particularly includes a base portion 78 and a plurality of flexible arms 80 extending therefrom combining with the base portion 78 to form a pocket. The arms 80 define flexible walls of the pocket extending from the base portion 78.

As least one of the arms 80 includes a hinged portion 82 allowing for outward deflection of the arm 80. The hinged portion, as shown in Figure 9, can be a recess cut into the base portion 78 adjacent the arm 80 to allow for increase outward flexibility of the arm 80 which includes the hinged portion 82. This allows for increased ease of insertion of the screw head 40''' into the pocket.

Figures 5-8 sequentially show the method of using the present invention for fixing a polyaxial screw 12''' therein. The screw itself 12''' is inserted into the bone by itself. This provides excellent visualization of screw placement since the larger body/insert assembly 10''' is pushed on the screw head after screw insertion into the bone.

As shown in Figure 5, the insert 70 is sufficiently collapsible to be snapped into the internal portion 72 of the body element 34"". This is accomplished by compressing the insert 70 and releasing it inside the internal portion 72. The assembly itself can be made from any durable material, such as carbon composites, nitinol, stainless steel, composite materials, plastics and plastic compositions or even resorbable materials. Preferably, titanium is used to minimize artifacts from x-rays and other diagnostic imaging systems. The combined assembly effectively provides the equivalent of a one piece assembly which is a significant improvement over prior art two piece assemblies or multiple piece assemblies necessary for only securing a screw head within a fixation device.

When the insert 7 is disposed within the first portion 74 of the internal portion 72, there is internal space to allow for slight expansion of the insert 70 therein. When the screw head 40"" is disposed into the internal portion 72, the screw head 40"" will effectively force the insert 70 into the first portion 74 thereby ensuring the ability of the pocket to expand sufficiently to allow insertion of the screw head 40"" into the pocket. Once the screw head 40"" is fully inserted into the pocket, the insert 70 snaps onto the screw head 40"". In this condition, polyaxial movement can be achieved.

Locking can be achieved in two manners. The body 30"" can be pulled up relative to the screw 12"" with an instrument (not shown) without the rod 20"" being in placed or pulled by the nut 26"" as the nut 26"" is tightened over the rod 20"". This provides the surgeon with the option of

adjusting the screw angle for abnormal anatomy and locking it prior to locking the rod 20''' to the assembly 10''' or locking the screw 12''' and rod 20''' interfaces simultaneously when correction is not required.

As shown in Figure 8, the U-shaped inner surface defining the
5 seat portion 16''' extends into the internal portion 72. Upon seating of the rod 20''', the inserted portion of the rod 20''', contacts a portion of the surface of the base portion 80 of the insert 70 for final seating of the insert 70 within the second portion 76 of the internal portion 72. As best shown in Figure 10, which shows a cross section of the body portion 30''', the second portion 76
10 includes a radially inwardly tapering surface. Thus, as the insert 70 is drawn into the second portion 76, the outer surface of the arms 80 of the insert 70 are progressively compressed about the screw head 40''' thereby effectively engaging and locking the screw head 40''' in position relative to the body portion 30'''. Upon final locking of the rod 20''' within the assembly 10''', as
15 described above, complete fixation is achieved.

Also significant with regard to this embodiment is the fact that the nut 26''', which includes a tapered treaded internal surface as discussed above, compresses the tapered threaded portion 14''' of the assembly 10''' against the rod 20'''. The nut 26''' will also seat against the rod 20''', but the
20 surface area engaging the rod 20''' will be vastly increased over the prior art, which increases the assembly to rod holding power. In fact, the nut against the rod is only a secondary locking means. The force of the portions 14''' against the rod 20''' is the primary locking mechanism. In other words, the rod 20'''

is engaged by the nut 26''', the body portion 30''', and the insert 70. Effective engagement of the insert 70 is significant as demonstrated in Figures 11 and 12.

Figure 11 shows a cross section of the assembly wherein a straight rod 20 is retained within the assembly. With such a straight rod 20, the rod 20 will push the insert 70 down until the rod 20 fits within the U-shaped channel of the body 30'''. It is ideal for the rod 20 to contact the edges of the body 30''' inside the U-shaped channel for maximum rod gripping strength. When the rod 20 is contoured, as shown in Figure 12, the insert 70 of the present embodiment can self-adjust and be pushed downward further than the edges of the body 30''' within the U-shaped cut-out to maximize rod contact. Such self adjustment is not at all found in the prior art since such U-shaped cut-outs in a body portion are fixed machine surfaces.

Figures 13-18 shown various permutations of the insert and body portions of the present invention. Figure 13 shows an insert 70 including arms 80 having smooth outside surfaces. This is an embodiment which is shown in the previously discussed figures. In Figure 14, the insert 70'' includes arms 80'' having an stepped outer surface 82. Such a step outer surface provides a stop for engaging the inner surface of the internal portion 72 to prevent the insert 70'' from moving beyond the desired engagement location. Figure 16 shows an insert 70'' including a radially inwardly tapered outer surface portion 84 for progressive engagement with the second portion

72. Figure 17 shows a further embodiment of the insert 70" combining the inward tapered surface 84" with the step 82".

Figure 15 shows a body portion 30"" wherein the second portion 76 includes a radially inwardly extending lip 86 at the peripheral edge thereof. Figure 18 shows a chamfered surface 88 a the peripheral edge of the second portion 76. both the lip 86 or the chamfered portion 88 provide further stops to ensure that once the insert member 70 is disposed within the internal portion 72, the insert 70 does not inadvertently exit therefrom.

The components for the assembly can be manufactured according to the following techniques, but every manufacturer has their own variations.

The body is made by first blanking the outer shape from round bar stock. By holding on the threaded end, or an extension to the threaded end (extra bar material), a hole is made into the opposite end. This hole is undersize relative to the taper to allow the taper to be but with a single tool. While the part turns in a lathe, a boring bar having a small cutting tip is introduced into the hole and the taper and recess cut. The threads are then cut, any extension cut off, and the slot either milled or cut be more EDM.

The insert is made by cutting the outside cylindrical shape with an extension to hold on in a lathe. A hole is drilled into one end and a boring bar with a small cutting tip used to enter the hole and cut the spherical seat. The outer slots and hinge details are cut by either a slitting saw or a wire EDM.

Another possibility for the insert is to have a U cut or indentation in the top of it for seating of the rod. This is not preferable, since orientation of the insert would then be necessary, but possible.

Another addition to the body at the threaded portion is to add a
5 recess in the side of the arms of the U on the inside for a rod to fit within. This would act as a guide for seating the nut with an instrument, as it would align the nut relative to the threads.

In combination, this last described embodiment provides a novel fixation assembly which can be either combined with the novel rod
10 retaining features described above or with other types of rod retaining features resulting in a simple effective and efficient means for fixing a screw member to a rod.

In accordance with this method, the locking mechanism is locked to the spherical head 40 of the bone fixation element 12" at a desired
15 angle prior to rod insertion or locked simultaneously by tightening of the nut member 26". This locking method and the mechanism used therewith is fully reversible and top loading.

The invention has been described in an illustrative manner, and it is to be understood that the terminology which has been used is intended to
20 be in the nature of words of description rather than of limitation.

Obviously, many modifications and variations of the present invention are possible in light of the above teachings. It is, therefore, to be

understood that within the scope of the appended claims the invention may be practiced otherwise than as specifically describe.

[illegible]

What is claimed is:

1. A spinal implant fixation assembly (10) comprising: bone fixation means (12) for fixation of the assembly (10) to a support; rod receiving means (14) operatively connected to said bone fixation means (12) and including a first seat (16) having an inner wall (18) for seating a portion of a rod (20) therein; and locking means (22) engaging said rod receiving means (14) for forcing said inner wall (18) to contour around and engage the rod (20) seated therein and for locking and fixing the rod (20) relative to said assembly (10).

10

2. An assembly as set forth in claim 1 wherein said rod receiving means (14) includes a tapered outer surface (24), said locking means (22) including an inner surface for being forced over and engaging said outer tapered surface (24) and inwardly deflecting said rod receiving means (14) about said first seat (16) as said locking means (22) further engages said tapered outer surface (14).

3. An assembly as set forth in claim 2 wherein said tapered outer surface (24) is further defined as a tapered threaded surface (24), said locking means (22) including an inner threaded surface (20).

20

4. An assembly as set forth in claim 3 wherein said rod receiving means (14) includes a body portion (30) having two arms (32,34) extending therefrom and being substantially parallel relative to each other, said two arms (32,34) and body portion (30) forming a U-shaped inner surface defining said first seat, said arms (32,34) including said tapered threaded surface (24).

5. An assembly as set forth in claim 1 wherein said fixation means is further defined as bone fixation means for fixing said assembly (10) to a bone.

6. An assembly as set forth in claim 5 wherein said body portion (30) includes said bone fixation means (12) extending therefrom at a predetermined angle relative to said U-shaped inner surface (18) defining said first seat (16).

7. An assembly as set forth in claim 6 wherein said bone fixation means (12) includes a hook portion (38) extending from said body portion (30') and being integral therewith.

8. An assembly as set forth in claim 6 wherein said bone fixation means includes a screw portion (36) extending from said body portion (30) and being integral therewith.

5

9. An assembly as set forth in claim 5 wherein said bone fixation means (12") includes a head portion (40), said rod receiving means (14") including a second seat (44) for seating said head portion (40) therein, said second seat (44) including an outer surface (50) thereabouts, said locking means (22") including a skirt engaging and radially inwardly deflecting said outer surface of said second seat portion (42) for first locking and fixing said head portion (40) within said second seat (44) prior to said locking means (22") locking and fixing the rod (20") within the first seat (16").

15

10. An assembly as set forth in claim 9 wherein said rod receiving means (14") consists of a substantially tubular body including a pair of spaced, substantially parallel arms (32",34") extending therefrom and forming a substantially U-shaped seat defining said first seat (16"), said tubular body further including a socket portion including outwardly flaring flanges (46) having distal end portions flaring radially outwardly tapering surfaces (50) relative to a central axis of said rod receiving means defining

20

said outer surface (50) of said second seat (44), said skirt portion (52) engaging and inwardly deflecting said distally outwardly tapering surfaces to engage said socket portion with said head portion (40).

5 11. An assembly as set forth in claim 10 wherein said locking means includes a ring member (52) defining said skirt portion, said tapered outer surface (24") of said rod receiving means (12") being a tapered threaded surface, said locking means (22") further including a nut member (26") including an inner threaded surface (28") for engaging and inwardly deflecting
10 said tapered threaded surface (24").

 12. An assembly as set forth in claim 11 wherein said head portion (40) is substantially spherical, said socket portion being substantially spherical for seating and engaging said head portion (40) therein.

15 13. An assembly as set forth in claim 11 wherein said ring (52) includes an edge surface (58), said nut member (26") including an abutment surface (60) for abutting against said edge surface (58) as said nut member (26") is threaded onto said tapered threaded portion (24") to force said ring
20 member (52) over said outer surface of said socket portion.

14. An assembly is set forth in claim 9 wherein said second seat (44) includes gripping means for gripping said head portion (40) within said second seat (44).

5

15. A method for locking a rod (20,20") to a bone by fixing a rod seating member (14,14'14") to a bone; seating a portion of a rod (20,20") within a substantially U-shaped seat (16,16") of the seating member (14,14'14"), and locking the rod (20,20") within the U-shaped seat (16,16") while engaging and contouring at least a portion of the U-shaped seat (16,16") about the rod (20,20").

16. A method as set forth in claim 15 further including the steps of fixing a bone fixation member (12") to a bone; locking and fixing a rod seating member (14") to a head portion (40) of the bone fixation member (12"), and then locking the rod (20") within the U-shaped seat (16").

17. A method as set forth in claim 16 wherein said locking and fixing step is further defined as forcing a ring member (52) over an outwardly

flared portion (46) of a seat portion (44) to lock and fix the head portion (40) of the bone fixation member (12") therein.

18. A method as set forth in claim 16 wherein said step of
5 locking the rod (20") within the U-shaped seat (16") is further defined as enlarging an inner threaded surface (28") of a nut member (26") over a tapered outer threaded surface (24") of the U-shaped seat (16") to force the ring (52) over the outer surface (50) of the seat portion (44) to lock and fix the head portion (40) of the bone fixation member (12") therein while simultaneously
10 deforming the inner surface of the U-shaped seat (16") about the rod (20") seated therein.

19. A spinal implant fixation assembly (10) comprising: bone fixation means (12) for fixation of the assembly (10) to support; rod receiving
15 means (14) operatively connected to said bone fixation means (12) and including a first seat (16) for seating a portion of a rod therein; and self-locking means (22) disposed about said rod receiving means (14) for securing and self-locking the rod (20) seated within said first seat (16) and fixing the rod (20) relative to said assembly (10).

20

20. An assembly as set forth in claim 19 wherein said self-locking means including an outer tapered surface (24) of said rod receiving

means (14) and a nut member (26) having an inner surface for being forced over and engaging said outer tapered surface (24).

21. An assembly as set forth in claim 20 wherein tapered outer
5 surface (24) is further defined as a tapered thread surface (24) said nut member (26) including an inner threaded surface (20).

22. A spinal fixation assembly 10^{'''} comprising; screw head
receiving means 70 for retaining a head 40^{'''} of a screw 12^{'''} therein, said
10 screw head receiving means 70 being movable within said assembly 10^{'''}
between a locked position entrapping the screw head 10^{'''} and an unlocked
position wherein the screw head 10^{'''} enters or escapes.

23. An assembly as set forth in claim 22 wherein said assembly
15 10^{'''} includes a body 30^{'''} including an internal position 72, said screw head
receiving means 70 including an insert member including a seat 44^{'''} for
seating the screw head 40^{'''} therein, said insert being movable within said
internal position 72 between said locked and unlocked positions.

20 24. An assembly as set forth in claim 23 wherein said seat 44^{'''}
includes a base portion 78 and a plurality of flexible arms 80 extending
therefrom combining with said base position 78 to form a pocket, said arms 80
defining flexible walls of said pocket extending from said base portion 78.

25. An assembly as set forth in claim 24 wherein at least one of said arms 80 includes a hinge portion 82 for allowing outward deflection thereof.

5 26. An assembly as set forth in claim 25 wherein said internal portion includes stop means for engaging an outer surface of said arms 80 to retain said insert member within said internal portion.

10 27. An assembly as set forth in claim 26 wherein said body portion 30"" includes rod retaining means for retaining a rod therein, said internal portion 72 including a first portion adjacent to said rod retaining means and a second portion extending from said first portion said first portion having an inner surface recessed radially outwardly relates to said second portion.

15 28. An assembly as set forth in claim 27 wherein said second portion includes a radially inwardly extending lip at an end thereof most distal relative to said first portion.

20 29. An assembly as set forth in claim 27 wherein said second position includes an end edge most distal relative to said first portion, said end edge being chamfered radially thereabout.

30. An assembly as set forth in claim 27 wherein said arms of said insert member includes an outer surface including engagement means for engaging an inner surface of said internal portion.

5 31. An assembly as set forth in claim 30 wherein said internal portion includes an annular shoulder between said first and second portions, said outer surface of said arms including a step defining said engagement means for engaging said shoulder to prevent said insert from moving beyond a desired engagement location.

10 32. An assembly as set forth in claim 31 wherein said arms have an outer surface tapering inwardly away from said step.

15 33. An assembly as set forth in claim 30 wherein said arms have an outer surface tapering inwardly away from said base portion.

20 34. An assembly as set forth in claim 30 wherein said body includes a neck portion, said rod retaining means including two opposed U-shaped seats extending into said neck portion, said U-shaped seat having a bottom portion thereof extending into said internal portion such that a rod seated in said U-shaped seat abuts against said insert member disposed within said first position and frees said insert member into said second portion, said outer walls of said arms engaging and being forced radially inwardly by said

second portion to collapse and engage a screw head disposed within said pocket.

1. ~~35~~. An insert for retaining a screw head in a spinal fixation assembly, said insert comprising:

a base portion and a plurality of flexible arms extending therefrom combining in with said base portion to form a pocket, said arms defining flexible walls of said pocket extending from said base.

2. ~~36~~. A body member of a spinal fixation assembly comprising:

rod receiving means for receiving a portion of a rod member therein; and

- an internal portion for movably retaining a screw head receiving insert therein.

3. ~~37~~. An assembly as set forth in claim ~~36~~² wherein said internal portion includes stop means for engaging an outer surface of the insert to retain the insert therein.

4. ~~38~~. An assembly as set forth in claim ~~36~~² wherein said body portion includes rod retaining means for retaining a rod therein, said internal portion including a first portion adjacent to said rod retaining means and a

second portion extending from said first portion, said first portion having an inner surface recessed radially outwardly relates to said second portion.

5 ~~39~~⁴. An assembly as set forth in claim ~~38~~⁴ wherein said second portion including a radially inwardly extending lip at an end thereof most distal relates to said first portion.

10 ~~40~~. An assembly as set forth in claim 29 wherein said second position includes an end edge most distal relative to said first portion, said end edge being chamfered radially thereabout.

6 ~~41~~. A spinal fixation assembly comprising:
a body member including an internal portion and an insert member including a screw head receiving pocket having an expanded condition to receive and release a screw head and a contracted condition for
15 fixedly engaging a screw head therein, said internal position movably containing said insert member between a first portion of said internal portion wherein said insert member is in said expanded condition and a second portion wherein said insert member is in said contracted condition.

20 ~~42~~⁷. An assembly as set forth in claim ~~41~~⁶ wherein said first portion radially outwardly recessed relative to said second position.

43. A method of retaining a screw head in a spinal fixation assembly by;

5 inserting a screw head into an expanded pocket of an insert contained within a first portion of an internal portion of a body member wherein the internal portion includes the first portion which is radially outwardly recessed relative to a second portion and;

10 moving the insert into the second portion, which comprises the pocket of the insert, into a contracted condition to fixedly engage the screw head within the pocket.

44. An method as set forth in claim 43 including the further steps of disposing a portion of a rod member into a seat portion of the body member, abutting the disposed portion of the rod member against the insert member which is disposed in the first portion in the expanded condition and
15 moving the insert into the second position, the rod member locking the insert in the second portion.

45. An method as set forth in claim 44 further including the
20 steps of inserting a non-straight portion of the rod into the seat portion and further compressing the insert member into the first portion.

8 46. A method of fixing a rod within a spinal fixation assembly

by;

disposing a portion of a rod member into a seat portion of a body member of the assembly; and

5 compressing the portion of the rod member against a compressible insert within the seat portion, the insert gripping portion of the rod.

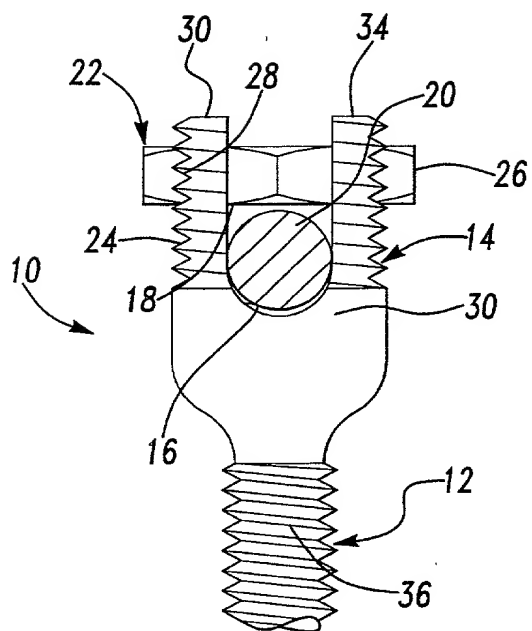


Fig-1

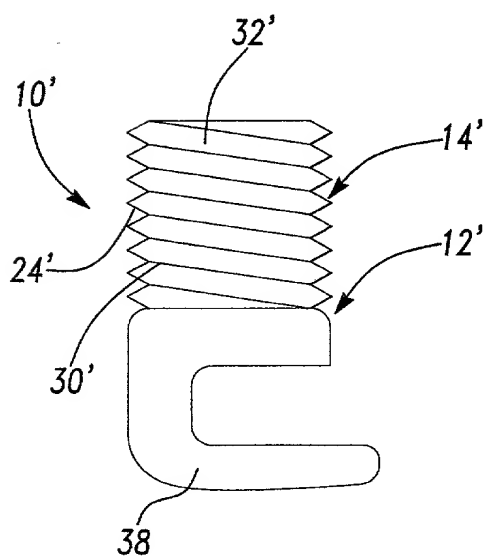


Fig-2

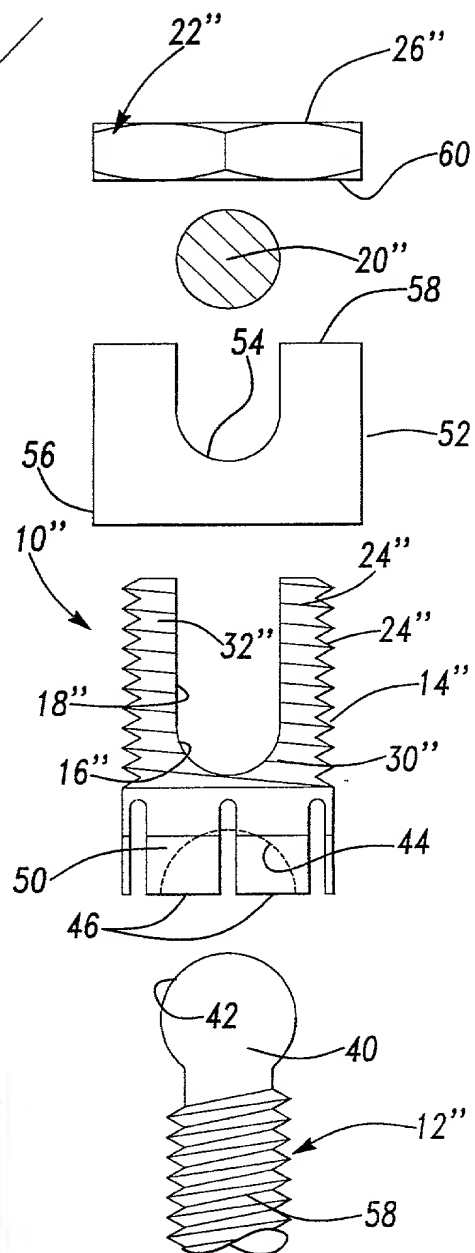
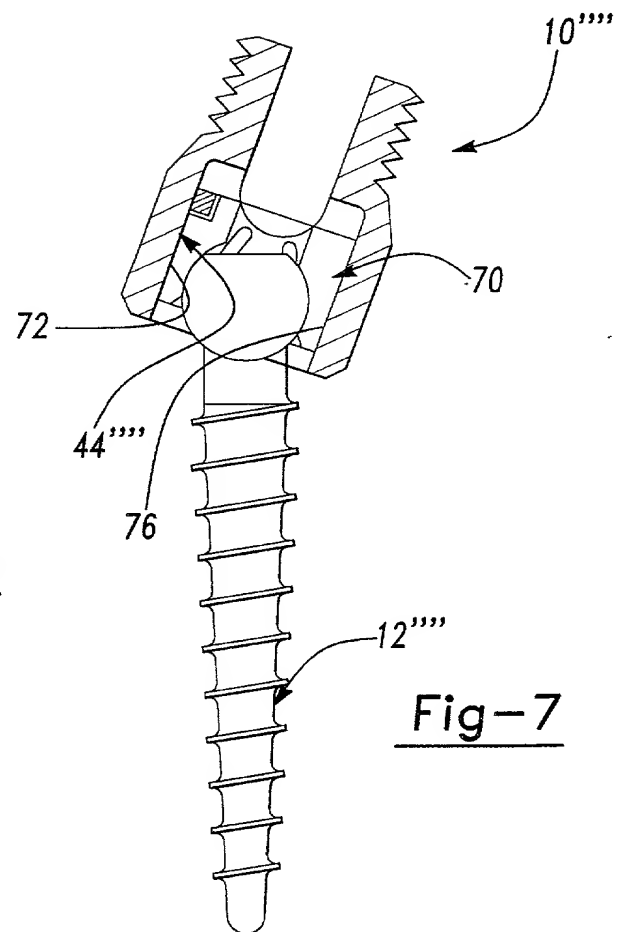
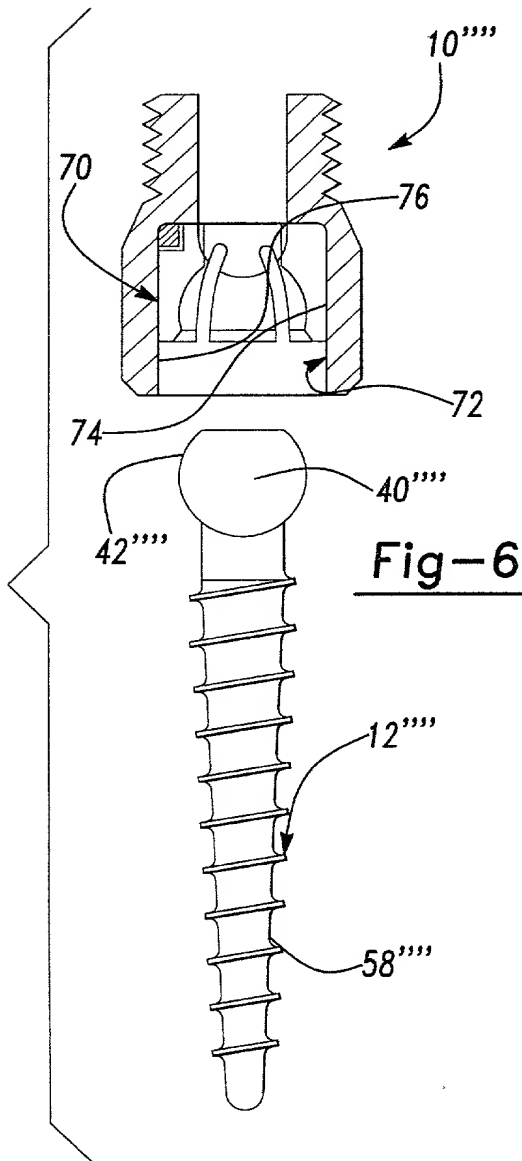
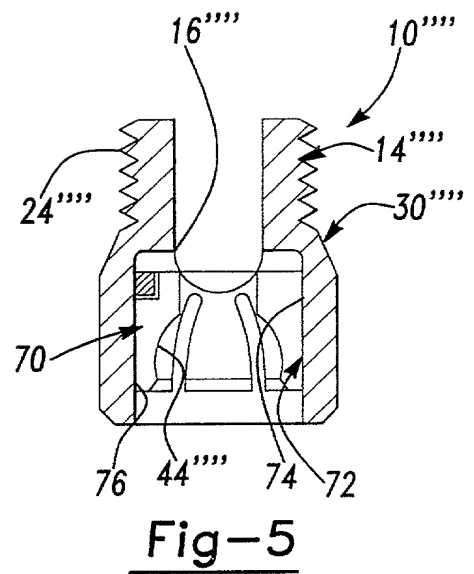
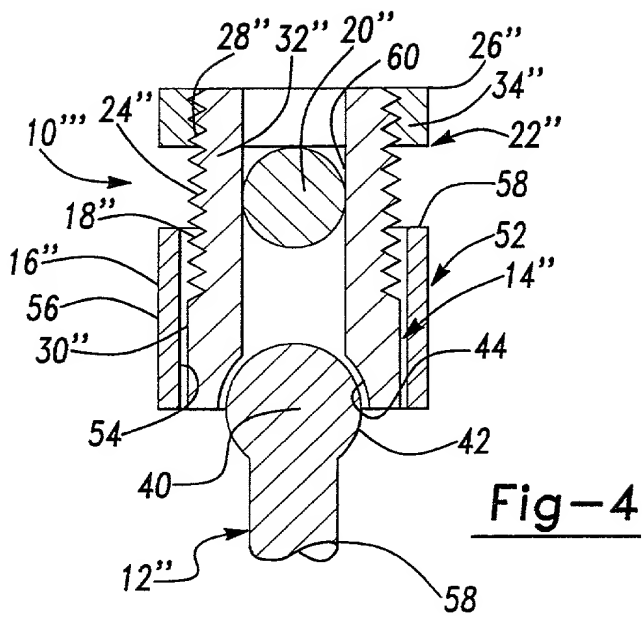
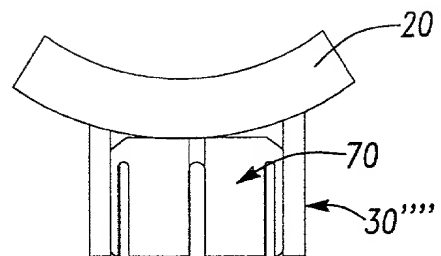
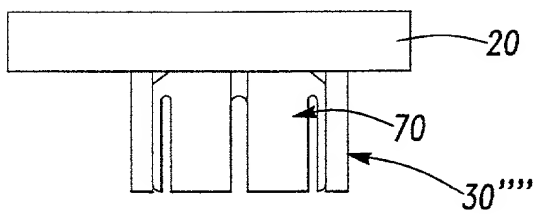
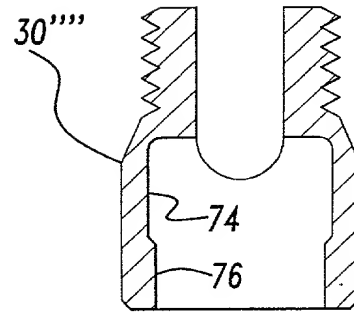
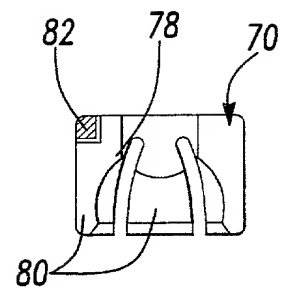
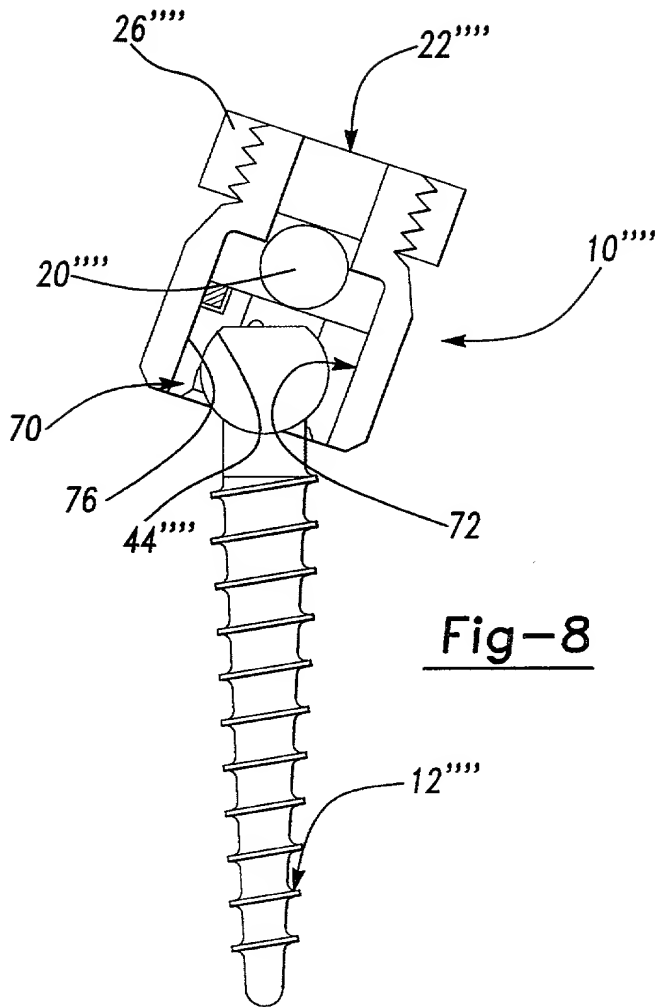


Fig-3





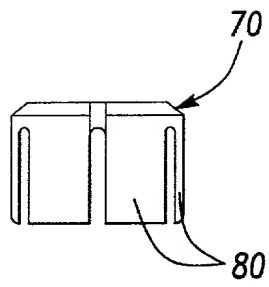


Fig-13

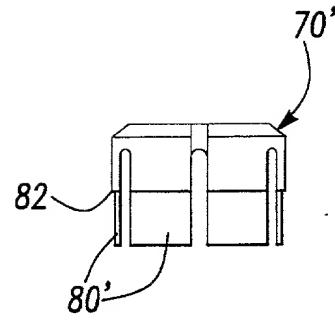


Fig-14

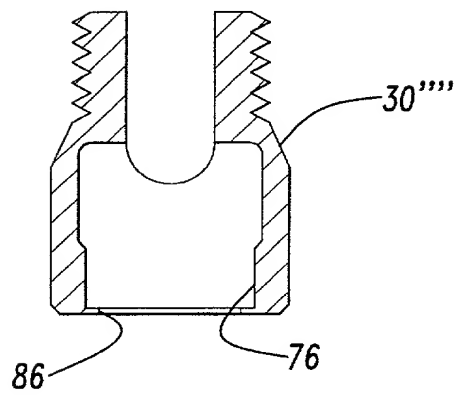


Fig-15

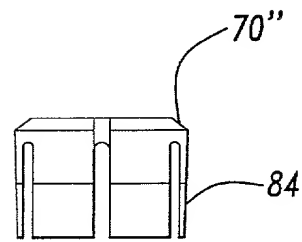


Fig-16

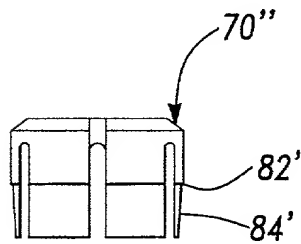


Fig-17

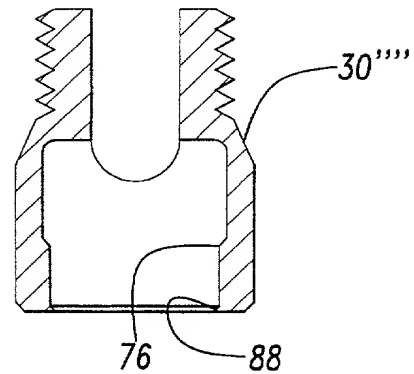


Fig-18

COMBINED DECLARATION AND POWER OF ATTORNEY

(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL,
DIVISIONAL, CONTINUATION OR CIP)

As a below named inventor, I hereby declare that:

TYPE OF DECLARATION

This declaration is of the following type: (check one applicable item below)

☐ original
☐ design
☐ supplemental

NOTE: If the declaration is for an international Application being filed as a divisional, continuation or continuation-in-part application do not check next item; check appropriate one of last three items.

☐ national stage of PCT

NOTE: If one of the follow 3 items apply then complete and also attach ADDED PAGES FOR DIVISIONAL, CONTINUATION OR CIP.

☐ divisional
☐ continuation
☒ continuation-in-part (CIP)

INVENTORSHIP IDENTIFICATION

WARNING: If the inventors are each not the inventors of all the claims an explanation of the facts, including the ownership of all the claims at the time the last claimed invention was made, should be submitted.

My residence, post office address and citizenship are as stated below next to my name, I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

SPINAL IMPLANT FIXATION ASSEMBLY

SPECIFICATION IDENTIFICATION

the specification of which: (complete (a), (b) or (c))

(a) ☒ is attached hereto.
(b) ☐ was filed on _____ as _____ Serial No. 08/_____ or _____ Express Mail No., as Serial No. not yet known _____ and was amended on _____ (if applicable).

NOTE: Amendments filed after the original papers are deposited with the PTO which contain new matter are not accorded a filing date by being referred to in the declaration. Accordingly, the amendments involved are those filed with the application papers or, in the case of a supplemental declaration, are those amendments claiming matter not encompassed in the original statement of invention or claims. See 37 CFR 1.67.

(c) _____ was described and claimed in PCT International Application No. _____
_____ filed on _____ and as amended under PCT Article 19 on _____
_____ (if any).

ACKNOWLEDGMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations. § 1.56(a).

_____ In compliance with this duty there is attached an information disclosure statement 37 CFR 1.97.

PRIORITY CLAIM

I hereby claim foreign priority benefits under Title 35, United States Code, § 119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

(complete (d) or (e))

(d) ☒ no such applications have been filed.

(e) _____ such applications have been filed as follows

NOTE: Where item (c) is entered above and the International Application which designated the U.S. claimed priority check item (e), enter the details below and make the priority claim.

EARLIEST FOREIGN APPLICATION(S), IF ANY FILED WITHIN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

COUNTRY	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIM UNDER 35 USC 119
US	08/734,520	18.10.96	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
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			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO

ALL FOREIGN APPLICATION(S), IF ANY FILED MORE THAN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

POWER OF ATTORNEY

As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. (List name and registration number)

Kenneth I. Kohn Reg. No. 30,955
Ilene N. Montgomery Reg. No. 38,972

SEND CORRESPONDENCE TO

DIRECT TELEPHONE CALLS TO:
(NAME AND TELEPHONE NUMBER)

Kenneth I. Kohn
Kohn & Associates
30500 Northwestern Hwy
Suite 410
Farmington Hills, MI 48334

Kenneth I. Kohn
(810) 539-5050

DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

SIGNATURE(S)

Full name of sole or first inventor Marc Richelsoph
Inventor's signature *Marc Richelsoph*
Date 4/8/97 Country of Citizenship U.S.A.
Residence Memphis, Tennessee
Post Office Address 9394 Alex Dickson Cove
Memphis, Tennessee 38133

Full name of second joint inventor, if any _____
Inventor's signature _____
Date _____ Country of Citizenship _____
Residence _____
Post Office Address _____

CHECK PROPER BOX(ES) FOR ANY OF THE FOLLOWING ADDED
PAGE(S) WHICH FORM A PART OF THIS DECLARATION

- ____ Signature for third and subsequent joint inventors. Number of
pages added ____
- ____ Signature by administrator(trix), executor(trix) or legal
representative for deceased or incapacitated inventor. Number of
pages added ____
- ____ Signature for inventor who refuses to sign or cannot be reached by
person authorized under 37 CFR 1.47. Number of pages
added ____

* * *

- X Added pages to combined declaration and power of attorney for
divisional, continuation, or continuation-in-part (CIP)
application.
- X Number of pages added 1

* * *

- ____ Authorization of attorney(s) to accept and follow instructions from
representative.

* * *

If no further pages form a part of this Declaration then end this
Declaration with this page and check the following item

____ This declaration ends with this page.